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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,995	11/20/2001	Yacta Endo	3190-012	8810
33432	7590	07/26/2004	EXAMINER	
KILYK & BOWERSOX, P.L.L.C. 53 A EAST LEE STREET WARRENTON, VA 20186			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,995

Applicant(s)

ENDO ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 12, 14, 22 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-21 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Status of the Claims***

1. Claims 1-30 are pending.

Applicants' amendment filed April 15, 2004 is acknowledged, and applicants' response has been fully considered. Claims 1-7, 10, 11, 13 and 15-21 have been amended. Regarding the restriction requirement, applicants affirm the election of Group I, claims 1-11, 13, 15-21 and 23-29 with traverse. The traversal is on the grounds that claim 12 is dependent on claim 10, the subject matter of claim 12 should be included in the examination, and if claim 10 is found allowable, claim 12 should be rejoined so that it would then be dependent on allowable subject matter. Similarly, for the same reason, claims 14 and 22, as well as claim 30, which is dependent from claim 23, should be examined because there is no serious burden to include claim 30, at least claim 30 should be rejoined once claim 23 is found allowable (page 10 of the response). This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no search burden and/or the dependency of the claims. As such restriction is proper if two or more claimed inventions are either independent or distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups would require search of additional classes, e.g., if claims 12, 14 and 22 were included, it would require additional search of class 435, subclasses 283.1 and 286.3; and if claim 30 were included, it would require additional search of class 530, subclass 350. As indicated in the previous Office Action, the claims of these groups are directed to different inventions that are not linked to form a single general concept. In this instance, a protein such as insulin and human growth

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hormone produced by in vitro protein synthesis is known in the art, see Choi, et al., U. S. Patent 5,593,856, the protein cited in the art is not different from the protein indicated in the claimed invention (regarding product by process claim, see MPEP 2113). Thus, the special technical feature is known and the claimed subject matter does not define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Furthermore, the claims in the different groups do not have in common the same or corresponding technical features, e.g., Group I is directed to a preparation containing cell extract for cell-free protein synthesis and a method of cell-free protein synthesis, while Group II (claims 12, 14 and 22) is directed to an apparatus for the cell-free protein synthesis, and Group III (claim 30) is directed to a protein produced by in vitro protein synthesis. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper. Thus, claims 12, 14, 22 and 30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-11, 13, 15-21 and 23-29 are examined.

The requirement is still deemed proper and is therefore made FINAL.

Foreign Priority

2. The previous indication that the priority date is not perfected, is withdrawn in view of applicant's response at page 11 in the amendment filed April 15, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 4-11, 13, 15-21 and 23-29 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 11-14 in the amendment filed April 15, 2004.

4. The previous rejection of claims 1-11, 13, 15-21 and 23-28 under 35 U.S.C. 112, second paragraph, regarding "substantially", "deadenation", antecedent basis for the term "the method", "a preparation", "a material substance", "the substrate and others", is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 14-16 in the amendment filed April 15, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11, 15-21 and 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "the systems" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 1-11, 15-21 and 23-28 are also indefinite as to "an endosperm portion", it is not clear whether the whole endosperm or a portion of endosperm of the cell extract is excluded. Claims 2-11, 15-21 and 23-28 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

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7. Claim 4 recites the limitation "the inhibiting of said systems" in line 2. There is insufficient antecedent basis for this limitation in the claim, claim 1 only indicates the systems involved in inhibiting the cell extract's protein synthesis are excluded, it does not indicate the systems are inhibited. Claims 19 and 26 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

8. Claim 5 is indefinite as to "a substance is present which controls deadenylation of ribosomes", it is not clear whether the substance is from the cell extract or is added to the cell extract since claim 1 does not indicate the existence of the substance. Claims 20 and 27 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

9. Claims 10, 11 and 23-29 are indefinite because the claims lack essential steps in the method for cell-free protein synthesis. The omitted steps are the step of addition of indispensable compounds to the cell extract which excludes the endosperm and a step regarding how the protein synthesis is carried out using the cell extract and the indispensable compounds.

In response, applicants indicate with respect to definiteness, it only requires that the claims be clear and definite to one skill in the art (page 17 of the response). The response has been considered, however, the argument is not found persuasive because the claims, which are directed to a method of synthesizing protein, do not include any method steps to obtain the final product, without such method steps, it is not clear how the process is carried out in a method claim, e.g., claim 23 only cites using the preparation of claim 1; and claim 10 only cites utilizing the preparation of claim 1, a

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reaction vessel for molecular sieving, and a material substance as a moving phase, the claim does not indicate how the protein synthesis proceeds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 4, 5, 23, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Endou (JP-07203984, August 1995). The rejection is based on an electronic translation of the patent publication from Japan Patent Office. A formal English translation of the publication is attached.

Endou teaches a ribosome inactivation protein, named Torichin (tritin) found in wheat germ can inactivate ribosome by removing an adenine from 28S rRNA (paragraph 0019), and a wheat germ extract is prepared by removing Torichin activity by adding Torichin antibody to the affinity column (paragraph 0029, claims 1, 4 and 5). The efficiency of protein synthesis in a wheat germ cell-free protein synthesis system is increased by using Torichin antibody and removing neutralized Torichin (paragraphs 0031-0038, Drawings 2 and 3, Examples 2-3; claims 23, 26 and 27). Since claim 1 only indicates “an endosperm portion” of a cell extract is excluded, it does not specify what endosperm portion (e.g., the whole endosperm or a portion of endosperm) and what method is used to remove the endosperm portion, thus, the wheat germ extract prepared by removal of tritin with tritin antibody and the use of the germ extract in the protein synthesis meet the criteria of the claimed invention.

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In response, applicants indicate that a complete formal English translation has not been provided to the applicant, and the electronic translation of the Japanese Patent Office, which may not be accurate, thus the subsequent Office Action should be made to non-final due to these circumstances; since Endou only discloses a wheat germ extract prepared by adding tritin antibodies to an affinity column and removing tritin therewith, thus the extract has contaminants other than tritin derived from endosperm; and the comparison between the Endou's data (JP-07203984; Attachment 2) and the instant invention (PNAS 97, 559-564 (2000); Attachment 3) has been made, and it appears that the cell extract of the instant invention is more efficient in protein synthesis (3.4 fold increase verse 2.4 fold increase; pages 17-20 of the response). The response has been considered, however, the argument is not found persuasive because of the following reasons: Although the cell extract of Endou (JP-07203984) has contaminants other than tritin from endosperm, and its efficiency in protein synthesis is lower than that in the instant application as shown by the comparison (Attachments 2 and 3), however, the amended claim (e.g., claim 1) only indicates the cell extract exclude "an endosperm portion", it does not cite the limitation reflecting the difference between the two extracts (see the paragraph indicated above), thus the reference anticipates the claimed invention. Regarding the electronic translation and the formal translation of the Japanese patent (attached), it appears the content of the electronic translation of the Japanese patent is not ~~very~~ ^{very} different from the formal translation, and applicants have used the data presented in the electronic translation to respond to the rejection made by Examiner, thus, non-final Office Action will not considered because of these circumstances.

Conclusion

11. Claims 1-11, 15-21 and 23-29 are rejected, it appears claim 13 is free of prior art and is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
July 19, 2004

Jon P. Weber
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Primary Examiner